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EXAMINER	
CHEN, CATHERYNE	
ART UNIT	**PAPER NUMBER**
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,001	MUNISEKHAR, MEDASANI	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,18-26 and 28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,18-26 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, Claims 16, 18-26, and 28-30 are pending and examined on the merits.

Claims 1-15, 17, and 27 are canceled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Aug. 20, 2010 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 18-22, 24-26, and 28-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating psoriasis, does not reasonably provide enablement for treating all skin disorders such as xeroderma pigmentosum. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to treat all types of skin disorder for the invention to commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and the breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Limited amount of guidance and limited number of working examples in the specification

While the Specification recited damages in the skin produced by a stress situation, no specific type of skin disorder is recited to be prevented (page 7, lines 1-4).

Nature of the invention

There are many types of skin disorders with many different causes. The Specification only teaches treatments for skin disorder associated with allergic disease, classified in type I-IV allergies (page 1). However, skin disorders can de derived from genetic disorders. Thus it would be impossible to prevent someone from getting all types of skin disorders through genetic disposition, such as xeroderma pigmentosum (see http://dermnetnz.org/systemic/xeroderma-pigmentosum.html).

State of the prior art

There are many causes of skin disorder. It has been found that metabolic factors, such as hormonal levels; autoimmune factors that cause inflammation; mechanical injury; inherited traits that increase susceptibility; lifestyle factors, such as smoking or dirt, can cause skin disorders.

Relative skill level of those in the art

Those in the art would have a difficult time to treat all types of skin disorder because of the many causes of skin disorders. As in xeroderma pigmentosum, the cause is genetic mutation, which is difficult to manipulate in humans. Therefore, the relative skill level required would be high.

Predictability or unpredictability in the art

Because of the many causes of skin disorders, the unpredictability in the art would be high.

The breadth of the claims

The breadth of the claims is broad, particularly for treating a skin disorder that does not involve allergic reactions.

Applicant's claims are broadly drawn to a composition that is able to a skin disorder, without specifically limiting the skin disorder to psoriasis. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is

able to prevent the condition each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to treat all types of skin disorder for all potential causes of skin disorder. In addition, the art teaches treating the skin disorder xeroderma pigmentosum is not accepted as possible because many risk factors such as age, race and family history cannot be controlled (see http://dermnetnz.org/systemic/xeroderma-pigmentosum.html). Because applicant's specification does not show treating all types of skin disorder and the art acknowledges that treatment of xeroderma-pigmentosum is not currently possible, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually functions as claimed. Therefore, the claims are not considered enabled for the all types of skin disorders.

Response to Arguments

Claim Rejections - 35 USC § 103

Claims 16, 18-26, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over McEleney et al. (US 5680962), Durr et al. (US 5997889), McAtee et al. (US 5607980) and further in view of Knoll et al. (US 4822604) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

McEleney et al. teaches a lotion with pH 6.5 or less (column 3, lines 11-13) for topical use (column 3, line 37), with cationic chloride (column 6, line 41), quaternaries such as alkylbenzyldimethylammonium salts, heterocyclic ammonium salts (column 7, lines 11-12), and perfumes to impart desired fragrance such as vanilla (column 8, lines 64), for formulation into creams, lotions, sticks, gels, oils, and mousses (column 10, lines 1-2). Benzalkonium chloride is also known as alkyldimethylbenzylammonium chloride. Vanilla is the whole plant.

However, it does not teach the amounts of vanilla from about 0.1% to an amount less than 2% by weight, amount from about 0.001% to about 40% by weight of quaternary ammonium, amount from about 0.001% to about 10% by weight of ammonium chloride, and psoriasis.

Knoll et al. teaches a clear therapeutic care composition having a low pH and useful in the local treatment of psoriasis of the scalp (Abstract) with 1.00%, 1.50%, 0.75% ammonium chloride (column 4, line 43) and keratolytic stabilizing agent (column 5, line 8), pH range of about 3.0-6.5 (Claim 3). A method of treating psoriasis of the scalp (Claim 7).

As for concentration of vanilla, Durr et al. teaches composition to treat psoriasis (column 1, lines 33-35) with vanilla oil up to a total of 2% by volume (column 4, lines 45-47, 55) as a cream (Abstract).

As for concentrations of quaternary ammonium and cation chloride salt, McAtee et al. teaches a topical composition comprising from about 0.1-15% by weight of a cationic surfactant (Claim 1). Cationic surfactant can be stearamidopropyl dimethyl

ammonium chloride (column 8, lines 33, 43-44) and quaternary ammonium salt cetyl ammonium chloride (column 8, lines 46, 48). The composition can be formulated into creams, lotions, mousses, sprays, cleansers, bars, gels, and the like (column 4, lines 4-7). Psoriasis is a skin problem with disorders of keratinization; therefore, there is need for topical skin care composition which gives skin smooth and elegant feel (column 1, lines 38-40, 53-55).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the solutions to treat psoriasis because Durr et al. teaches lotions with vanilla extract can be used to treat psoriasis. One would have been motivated to make use lotions with vanilla extract for the expected benefit of treating psoriasis. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use ammonium chloride because Knoll et al. teaches lotions with ammonium chloride can be used to treat psoriasis. One would have been motivated to make use lotions with ammonium chloride for the expected benefit of treating psoriasis. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising vanilla from about 0.1% to an

amount less than 2% by weight, amount from about 0.001% to about 40% by weight of quaternary ammonium, amount from about 0.001% to about 10% by weight of ammonium chloride combination for the following reasons. The references do teach the composition for treating topical skin and psoriasis. Knoll et al. teaches a clear therapeutic care composition having a low pH and useful in the local treatment of psoriasis of the scalp (Abstract) with 1.00%, 1.50%, 0.75% ammonium chloride (column 4, line 43) and keratolytic stabilizing agent (column 5, line 8), pH range of about 3.0-6.5 (Claim 3). A method of treating psoriasis of the scalp (Claim 7). As for concentration of vanilla, Durr et al. teaches composition to treat psoriasis (column 1, lines 33-35) with vanilla oil up to a total of 2% by volume (column 4, lines 45-47, 55) as a cream (Abstract). As for concentrations of quaternary ammonium and cation chloride salt, McAtee et al. teaches a topical composition comprising from about 0.1-15% by weight of a cationic surfactant (Claim 1). Thus, it would have been obvious to make a concentrated composition containing vanilla extract, quaternary ammonium, and ammonium chloirde for use as a topical agent to treat psoriasis. Additionally, the amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It

would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, especially within the ranges taught by the reference. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Applicant argues that McEleney et al. does not teach treatment for psoriasis.

In response to Applicant's argument, Applicant's claim is drawn toward a treatment for a skin disorder, McEleney et al. teaches ingredients for topical use to treat sunburn (column 1, lines 14-22), which is a skin disorder of blistered and flaked skin (see Applicant's response of Aug. 20, 2010, middle of page 3). Topical creams are applicable to skin, which is the situs for psoriasis. As for treatment of psoriasis, Knoll et al. teaches a clear therapeutic care composition having a low pH and useful in the local treatment of psoriasis of the scalp (Abstract) with 1.00%, 1.50%, 0.75% ammonium chloride (column 4, line 43) and keratolytic stabilizing agent (column 5, line 8), pH range of about 3.0-6.5 (Claim 3). A method of treating psoriasis of the scalp (Claim 7). Durr et al. teaches composition to treat psoriasis (column 1, lines 33-35) with vanilla oil up to a total of 2% by volume (column 4, lines 45-47, 55) as a cream (Abstract). McAtee et al. teaches a topical composition comprising from about 0.1-15% by weight of a cationic surfactant (Claim 1). Cationic surfactant can be stearamidopropyl dimethyl ammonium chloride (column 8, lines 33, 43-44) and quaternary ammonium salt cetyl ammonium chloride (column 8, lines 46, 48). The composition can be formulated into creams, lotions, mousses, sprays, cleansers, bars, gels, and the like (column 4, lines 4-7).

Psoriasis is a skin problem with disorders of keratinization; therefore, there is need for topical skin care composition which gives skin a smooth and elegant feel (column 1, lines 38-40, 53-55). Thus, an artisan of ordinary skill would reasonably expect that agents for psoriasis could be used as the types of ingredients for topical skin taught by the references. This reasonable expectation of success would motivate the artisan to use vanilla extract, quaternary ammonium, and ammonium chloride in the reference composition. Thus, using the ingredients for treating psoriasis is considered an obvious modification of the references.

Applicant argues that vanilla amount taught is not use as at therapeutic concentration.

In response to Applicant's argument, Applicant's claim of vanilla is in an amount from about 0.1% to less than 2% by weight. Durr et al. teaches composition to treat psoriasis (column 1, lines 33-35) with vanilla oil up to a total of 2% by volume (column 4, lines 45-47, 55) as a cream (Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising from about 0.1% to less than 2% by weight of the active agent. Thus, it would have been obvious to make a concentrated composition containing the vanilla to treat psoriasis for use as a method for treating a skin disorder such as psoriasis. Additionally, the amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, especially within the ranges taught by the reference. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michele Flood/

Primary Examiner, Art Unit 1655